

REMARKS

Claim 1 and Claims 61-79 are pending in this Application.

Claim 1 and Claims 61-79 have been rejected.

No claims have been allowed.

Claims 61, 63, 65 and 74 have been amended.

Claim 1 and Claims 61-79 remain in this Application.

Reconsideration of the claims is respectfully requested.

Specification

On Page 2 of the November 26, 2002 Office Action, the Examiner objected to the disclosure of the patent application for certain informalities. The Applicant has amended the text of the specification to correct certain typographical errors in the specification and to correct the informalities identified by the Examiner. No new matter has been added to the specification as a result of these amendments.

Drawings

On Page 2 of the November 26, 2002 Office Action, the Examiner objected to the drawings of the patent application under 37 C.F.R. § 1.83(a). The Applicant directs the Examiner's attention to Figure 9 and to Figure 22. These figures show semicircular prostheses. The Applicant also directs the Examiner's attention to Figure 25. This figure shows an elliptical prosthesis. The specification clearly states that the prostheses of the present invention may have different shapes

(Page 25, Lines 8-9). The Applicant respectfully submits that the rejections directed to the drawings have now been overcome.

35 U.S.C. § 112, Second Paragraph

On Page 2 of the November 26, 2002 Office Action, the Examiner rejected Claims 61-79 under 35 U.S.C. § 112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant has amended Claims 61, 63, 65 and 74 to correct any indefiniteness in the above mentioned claims. The Applicant respectfully submits that this rejection has now been overcome.

35 U.S.C. § 101

On Page 3 of the November 26, 2002 Office Action, the Examiner rejected Claims 74-79 under 35 U.S.C. § 101 for reasons explained in the last paragraph of M.P.E.P. § 2105. The Examiner stated that this rejection may be overcome by making the revision to Claim 74 recommended in the paragraph concerned with the indefiniteness rejection. The Applicant has amended Claim 74 to remove the scleral pocket as a positively recited feature in the claim body. The Applicant respectfully submits that this rejection has now been overcome.

Double Patenting Rejections

On Page 3 of the November 26, 2002 Office Action, the Examiner rejected Claims 61-79 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of United States Patent No. 6,280,468 B1 (the “‘468 Patent”). The ‘468 Patent is commonly owned by the assignee of the present application. The Applicant is submitting a terminal disclaimer under 37 C.F.R. § 1.321, disclaiming any portion of the term of a patent issuing on this patent application exceeding the terminal date of the ‘468 Patent.

On Page 4 of the November 26, 2002 Office Action, the Examiner rejected Claims 61-79 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of United States Patent No. 6,007,578 (the “‘578 Patent”) or the claims of United States Patent No. 6,299,640 B1 (the “‘640 Patent”). The ‘578 Patent and the ‘640 Patent are commonly owned by the assignee of the present application. The Applicant is submitting a terminal disclaimer under 37 C.F.R. § 1.321, disclaiming any portion of the term of a patent issuing on this patent application exceeding the terminal date of the ‘578 Patent and the ‘640 Patent.

35 U.S.C. § 102(b) Claim Rejections

On Page 4 of the November 26, 2002 Office Action, the Examiner rejected Claims 61-68, 70, and 74-79 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,354,331 to *Schachar*. The Applicant respectfully traverses these rejections.

Section 102, in pertinent part, provides that a “person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.” It is axiomatic that anticipation of a claim under §102 can be found only if the prior art reference discloses every element of the claim. *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)).

Amended independent Claim 61 reads as follows:

61. [Amended] A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:
an elongated body having a first end, a second end, a first surface and a second surface, said first surface and said second surface being adapted to contact said sclera, and
means for expanding said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball. (Emphasis added).

A determination of anticipation, with respect to Claim 61, requires that each feature claimed therein be described in sufficient detail in the *Schachar* reference to enable one of ordinary skill in the art to make and practice the claimed invention.

The *Schachar* patent is directed to a scleral expansion band in the shape of a ring. It is evident from the drawings of the *Schachar* patent and from the text at Column 7, Lines 1-12, that the *Schachar* patent is directed to a device that forms a “complete band.” (*Schachar*, Column 7, Line 3). The drawings and the text of *Schachar* make it clear that the “complete band” is a ring.

The *Schachar* ring does not have a first end and a second end. The length of the *Schachar* ring may be adjusted by a “tangential screw mechanism” (*Schachar*, Column 7, Line 10). There is no disclosure, teaching or even a hint in *Schachar* that the tangential screw mechanism is an expansion means. The only function of the tangential screw mechanism is to adjust the circumference of the band. (*Schachar*, Column 7, Lines 10-11). It is the complete band that expands the sclera. The *Schachar* patent fails to disclose or even hint at the structure of the elongated body of the present invention. A ring-shaped “complete band” does not have a first end and a second end. These comments also apply to Claims 62-68, 70 and 74-79. The Applicant respectfully submits that the rejections under 35 U.S.C. § 102(b) have now been overcome.

35 U.S.C. § 103(a) Claim Rejections

On Pages 3- 4 of the November 26, 2002 Office Action, the Examiner rejected Claims 69 and 71-73 under 35 U.S.C. § 103(a) as being obvious in view of United States Patent No. 5,354,331 to *Schachar*. The Applicant respectfully traverses these rejections.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness

is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

The Applicant respectfully submits that the Patent Office has not established a *prima facie* case of obviousness with respect to Claim 69 and Claims 71-73 of the Applicant's invention. Claim 69 depends from Claim 66 which, in turn, depends from Claim 61. The Applicant directs the Examiner's attention to amended Claim 61 which shows novel and unique features:

61. [Amended] A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:

an elongated body having a first end, a second end, a first surface and a second surface, said first surface and said second surface being adapted to contact said sclera, and

means for expanding said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball. (Emphasis added).

For the reasons set forth above in connection with the rejections under § 102(b), the Applicant respectfully submits that the *Schachar* patent does not disclose, teach or even hint at the structure of the present invention. The Examiner stated that the dimensions recited in Claim 69 would have been obvious “from anatomical considerations” for the “plurality of parts” recited in Column 7, Line 2 of the *Schachar* patent. The Applicant respectfully traverses this assertion of the Examiner because the “plurality of parts” in *Schachar* form a “complete band” as previously described. There is no teaching, suggestion or hint in *Schachar* to use an individual part of the “plurality of parts” as a separate prosthesis. The *Schachar* patent teaches using the “plurality of parts” collectively as a “complete band.” Unlike the present invention, there is nothing in *Schachar* that suggests the dimensions of an individual separate prosthesis. The Applicant respectfully submits that the obviousness rejection of Claim 69 has been overcome.

With respect to Claims 71-73, the Examiner also stated that the use of an internal cavity filled with saline solution would have been obvious from the *Schachar* patent. The Examiner cited Column 6, Lines 4-45 and Column 6, Lines 45-64. The Applicant respectfully traverses these rejections. First, unlike the ring shaped “complete band” of the *Schachar* patent, the prosthesis of the present invention claimed in Claims 71-73 comprises an elongated body with a first end and a

second end. Second, there is nothing in the cited portion of the *Schachar* patent (or in any other portion of the *Schachar* patent) that discloses, suggests or even hints at the concept of having a prosthesis with an internal cavity filled with saline solution or the like. The “diversity of materials” cited in Column 6 of the *Schachar* patent do not include any liquids such as saline solution. The Applicant’s concept of using a prosthesis with an internal cavity filled with saline solution or the like is therefor not obvious in view of the *Schachar* patent. The Applicant respectfully submits that the obviousness rejections of Claims 71-73 have been overcome.

The Applicant therefore respectfully requests that Claim 1 and Claims 61-79 be deemed to be allowable claims and that Claim 1 and Claims 61-79 be passed to allowance.

The Applicant denies any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. The Applicant reserves the right to submit further arguments in support of its above-stated position, as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY


For the reasons given above, the Applicant respectfully requests reconsideration and allowance of pending claims and that this patent application be passed to issue. Any additional fees due by virtue of this Amendment should be charged to Deposit Account No. 50-0208. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting prosecution of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com.

Respectfully submitted,

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APPENDIX A
VERSION MARKED TO SHOW CHANGES MADE
IN THE SPECIFICATION

Page 1, Lines 9-10, has been amended as follows:

This application is a [continuation] continuation-in-part of prior U.S. Application Serial No. 09/061,168 filed on April 16, 1998, which issued as U. S. Patent No. 6,280,468 on August 28, 2001, which is a [continuation] continuation-in-part of prior U.S. Application Serial No. 08/846,975 filed on October 8, 1997, which issued as U.S. Patent No. 6,007,578 on December 28, 1999.

Page 9, Lines 12-13, has been amended as follows:

Figure 10 shows an end view of the prosthesis of Figure 9 [as indicated by the line 10-10].

Page 12, Line 12 to Page 13, Line 3, has been amended as follows:

According to the invention the effective working distance of the ciliary muscle is increased by implanting in pockets surgically formed in the sclera of the eye a plurality of prostheses designed to place an outward traction on the sclera in the region of the ciliary body. The relevant anatomy of the eye for locating the scleral pockets may be seen by reference to Figures 1-4. The outermost layer of the eye 100 comprises the white, tough sclera 102 which encompasses most of the globe and the transparent cornea 104, which constitutes the anterior segment of the outer coat. The circular junction of the cornea and sclera is the limbus 106. Within the globe of the eye, as illustrated in the cross-section of Figure 4, the crystalline lens 108 is enclosed in a thin membranous capsule and is located immediately posterior to the iris 112, suspended centrally posterior to the pupil 114 on the optical axis of the eye. The lens 108 is suspended by zonules [115] extending between the lens capsule at the equator 110 of the lens 108 and the ciliary body 116. The ciliary body 116 lies just under the sclera 102 (i.e., just inwardly of the sclera 102) and is attached to the inner surface of the sclera 102. As may be seen in Figure 4, the ciliary body 116 lies generally in a plane 130 defined by the equator 110 of the lens 108. The plane 130 can also be extended to intersect the sclera 102 whereby it forms a generally circular intersection located about 2 millimeters posterior to the limbus 106. The external muscles 118 of the eyeball control the movement of the eye.

Page 16, Line 18 to Page 17, Line 11, has been amended as follows:

Figures 9-10 illustrate a prosthesis of the invention having a curved platform adapted to be implanted in a scleral pocket that is curved to match the curvature of the eyeball. The prosthesis 300 of Figures 9-10 has a generally planar base 302, curved in the plane of the base 302, having an anterior edge 304, a posterior edge 306, and lateral ends 308 and 310. The inner face is provided with a ridge 314 extending along the length of the major dimension of the elongated curved base 302. Figure [11] 10 shows [an end] a side view of the prosthesis of Figure 9 showing the outer face 316, the ridge 314 and a notch 318 on the inner face 312 of the prosthesis. The curvature of the base is chosen to provide at least an approximate match for the curvature of the adjacent structures on the surface of the sclera, e.g., the limbus 106, adjusted for the distance of the scleral pocket 120 and prosthesis 300 from the limbus 106. Figure 3 shows a front elevational view of an eye provided with curved scleral pockets 120 to accommodate a curved prosthesis 300 of the type illustrated in Figures 9 and 10.

Page 17, Lines 12-24, has been amended as follows:

Figures 11-13 show an embodiment of the invention wherein the anterior portion is tapered from the ridge to the anterior edge. Figure 11 shows a plan view of the prosthesis 400 having a base 402 with an anterior edge 404, a posterior edge 406, and lateral ends 408 and 410. The outer face 416 is smooth and adapted to be placed against the inner surface of the outer wall 128 of a scleral pocket 120. The inner face 412 is provided with a ridge 414 extending along the length of the major dimension of the elongated base 402. Figure 12 shows a front elevational view of the prosthesis of Figure 11 showing the flat, smooth outer face [412] 416 of the prosthesis. Figure 13 shows an end view of the prosthesis of Figure 11 showing the outer face [412] 416 and the ridge [410] 414 on the inner face [414] 412 of the prosthesis 400. In this embodiment the ridge [410] 414 tapers toward the anterior edge 404 of the prosthesis.

Page 18, Line 3 to Page 19, Line 1, has been amended as follows:

Figures 14-16 show a preferred embodiment of the prosthesis in which the ridge member includes extensions beyond the ends of the base member which lie on the surface of the sclera adjacent to the scleral pocket and help to stabilize the prosthesis. Figure 14 shows a plan view of this embodiment 500 having a base 502 with an anterior edge 504, a posterior edge 506, and lateral ends 508 and 510. The inner face 512 is provided with a ridge 514. The ends 508 and 510 of the [base 502] ridge 514 extend slightly beyond the ends of the [ridge 514] base 502. Accordingly, the ends 508 and 510 of the [base 502] ridge 514 will extend beyond the ends of the pocket 120 and lie on the surface of the sclera 102. Figure 15 shows a front elevational view of the prosthesis of Figure 14 showing the flat, smooth outer face 516 of the prosthesis and the ends 508 and 510 of the

[base 502] ridge 514 extending beyond the ends of the [ridge 514] base 502. Figure 16a shows an end view of the prosthesis of Figure 14 showing the smooth outer face [512] 516 and the ridge [510] 514 on the inner face [514] 512 of the base 502, as well as a notch 518. Figure 16b shows an end view of an alternate embodiment of the prosthesis 500 wherein the base 502 does not taper all the way to the posterior edge 506. Evidently, the thickness of the posterior edge 506 may vary from a relatively sharp posterior edge as shown in Figure 16a to a relatively thick posterior edge as shown in Figure 16b, or even thicker if it is advantageous.

Page 19, Line 2 to Page 20, Line 1, has been amended as follows:

Figures 17-20 illustrate an embodiment of the prosthesis that is hollow and made from a plastic or elastomeric material and filled with a liquid. Figure 17 shows a plan view of this embodiment 600 having a base 602 with an anterior edge 604, a posterior edge 606, and lateral ends 608 and 610. The inner face 612 is smoothly rounded and rises to a crest 614 that serves to support the prosthesis on the inner wall 126 of the scleral pocket 120 in the same way as the ridge member of other embodiments of the invention. Figure 18 shows a front elevational view of the prosthesis of Figure 17 showing the flat, smooth outer face [614] 616 of the prosthesis. Figure 19 shows a cross section of the prosthesis of Figure 17 taken along the line 19-19. The cross-section shows the flexible wall 612 of the prosthesis as well as the flat outer face 616, and the crest 614. The cross section also shows the filling liquid 620. Figure 20 shows an end view of the prosthesis of Figure 17 showing the outer face 616 and the crest or ridge 614 on the inner face 612 of the prosthesis 600. The hollow prosthesis is filled with liquid, typically by injecting the liquid through an end 608 or 610. The prosthesis may be filled with more or less liquid in order to adjust the thickness between the outer face 616 and the crest or ridge 614 to provide more or less traction on the sclera at the anterior margin 122 of the scleral pocket or belt loop 120.

Page 28, Lines 7-19, has been amended as follows:

Figures 2 and 3 show front elevational views of an eye 100 showing the scleral pockets 120 formed at approximately the 45° meridians of the eye, i.e., approximately halfway between the vertical and horizontal meridians of the globe. This location is preferred because it avoids interference with structures of the eye that are located generally on the vertical and horizontal meridians. Figure [2] 3 shows the use of curved scleral pockets 120 to permit the use of curved prostheses of the type illustrated in Figures 9 and 10. Figure [3] 2 shows the use of straight scleral pockets 120. Such straight pockets are somewhat simpler to prepare surgically. For many patients the use of straight prostheses can provide adequate treatment of their presbyopia.